

*Helicobacter pylori*  
Genedia™

**A Comparison of Accuracy between A New Commercial ELISA Test,  
Genedia™ Test and Other Commercial ELISA Tests for Serological  
Diagnosis of *Helicobacter pylori* Infection in Korea**

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**Background/Aims:** A new commercial enzyme linked immunosorbent assay (ELISA) test using Korean *Helicobacter pylori* (*H. pylori*) as an antigen, Genedia™ test, was compared to other serologic tests for *H. pylori* infection. **Methods:** Among two hundred seventy three subjects, *H. pylori*-positive group was consisted of 132 patients (50 peptic ulcer diseases, 52 chronic gastritis, and 30 gastric cancers) and *H. pylori*-negative group was consisted of 141 patients (121 adults and 20 pediatric patients). Endoscopic antral biopsy specimens were obtained for microscopy and rapid urease test (CLO™ test). We also performed Genedia™ IgG, IgA ELISA, G.A.P IgG, IgA ELISA, and Cobas-core IgG EIA. *H. pylori* infection was determined when *H. pylori* was detected histologically or the results of CLO™ tests were positive. **Results:** The sensitivities and specificities of the serologic tests were 96.2% and 46.1% in Genedia™ IgG, 91.7% and 52.5% in Genedia™ IgA, 81.8% and 46.8% in G.A.P IgG, 25.0% and 85.1% in G.A.P IgA, 96.9% and 38.6% in Cobas-core test, respectively. In *H. pylori*-negative pediatric patients, the specificity of the tests was 80% in Genedia™ IgG, 95% in Genedia™ IgA, 60% in G.A.P. IgG, 100% in G.A.P IgA, and 75% in Cobas-core test. **Conclusions:** In Korea, Genedia™ test was comparable or superior to general serologic tests used for diagnosing *H. pylori* infection. However, it is necessary to improve the specificity of the Genedia™ test. (Kor J Gastroenterol 2000;36:20 - 28)

**Key Words:** *Helicobacter pylori*, Korean *H. pylori*, Serologic diagnosis, ELISA test, Genedia™ test

: 2000 1 31 , : 2000 3 2  
: , 120-752, 134 ,  
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가 , 13  
가 .  
*Helicobacter pylori*( *H. pylori*) *H.*  
가  
가  
 , *H.*  
*pylori* 가  
 . *H. pylori*  
 , rapid urease test 1.  
*H. pylori*  
 , 273  
가  
 .12  
가 ,  
 , 가  
가 가  
34 . 30 132 , 118  
가 가 14  
가 가 , 가  
71 , 가 61 47.7 .  
 .59 CLOTM 가  
가 121 20 (8.1 -13.2 )  
가 74 , 가 67  
1996 Digestive Health Initiative 42.9 (Table 1). *H. pylori*  
 ,  
( ).  
2.  
*H. pylori* 가  
가 가 .  
1)  
-70 ,  
*H. pylori*  
Genedia™ *Helicobacter pylori* IgG ELISA,  
Genedia™ *Helicobacter pylori* IgA ELISA, Bio-Rad  
G.A.P test IgG kit, G.A.P test IgA kit Roche  
Cobas core anti-*H. pylori* IgG EIA(2nd gene-  
ration) kit .  
(sensitivity) (specificity)  
가  
, 10-12 *H. pylori* ,

**Table 1.** Determination of *H. pylori* Infection according to the Histology and CLOTM Test

<i>H. pylori</i> infection	Histology	CLOTM test	No. of cases (n=273)	Age (mean, yr)
Positive	+	+	118	47.7
	+	-	1	
	-	+	13	
Negative	-	-	141	42.9
Total			273	45.7

kit	<i>H. pylori</i>	100 $\mu$ l	well	25	10
				50 $\mu$ l	
(borderline)		20		(colorimetry)	450 nm
<i>H. pylori</i> IgG					
(1) Genedia™ <i>Helicobacter pylori</i> IgG, IgA ELISA		IgA	가	<i>H. pylori</i> IgG	
		가	kit manual	12.5 unit/ml	
			, 12.5 unit/ml		
37	1	well	200 $\mu$ l		
		5			
(3) Cobas-core™ anti- <i>H. pylori</i> IgG EIA					
IgG	(goat anti-human IgG enzy-				
me conjugate)	200 $\mu$ l	well	37	<i>H. pylori</i>	bead
30		5		<i>H. pylori</i>	가
	Tetramethylbenzidine	가			
200 $\mu$ l	well		peroxidase	가	anti-human IgG
30		(stop solution)	100	bead	-
$\mu$ l		15			conjugate
	620 nm,	450	methylbenzidine	가	
nm	cut-off (		37	15	, bead
	+ 0.4)		<i>pylori</i> IgG		<i>H.</i>
	, cut-off				450 nm
				cut-off (	+ 0.07)
					, cut-off
(2) G.A.P test IgG, IgA ELISA					
			(12.5, 25,		
50, 100 U/ml)	IgG		2)		
100 $\mu$ l	well	25	60	5 cm	
		3	IgG	H&E	CLOTM
IgA	(anti-IgG or IgA enzyme conjugate)	가		<i>H. pylori</i>	
100 $\mu$ l	well	25	30	H&E	
	3			formalin	H&E Giemsa

, grade 2 . G.A.P IgG 98

1 *H. pylori* 24 .

, grade 2 G.A.P IgA 33

, grade 3 . Cobas-core IgG 127 ,

(foveola) 5 GenediaTM IgG

, grade 1 *H. pylori* 141

GenediaTM

IgG 65 , 76

3) CLOTM test , GenediaTM IgA 74 ,

67 , G.A.P IgG

CLOTM test kit 3 , 24 66 , 75 ,

G.A.P IgA 120 , 21

, Cobas-core IgG 54

, 86 (Table 2).

2.

(Table 3),

1. GenediaTM IgG

*H. pylori* 가 96.2% 46.1%, Gene-

(Table 2). *H. pylori* diaTM IgA 91.7% 52.5% .

132 GenediaTM IgG 127 IgG GAP IgG

, GenediaTM IgA 121

**Table 2.** Results of Serologic Tests for *H. pylori* Infection

	132 <i>H. pylori</i> positive		141 <i>H. pylori</i> negative	
	Seropositive	Seronegative	Seropositive	Seronegative
Genedia IgG	127	5	76	65
Genedia IgA	121	11	67	74
G.A.P IgG	108	24	75	66
G.A.P IgA	33	99	21	120
Cobas-core IgG	127	5	86	54

**Table 3.** Comparison of Serologic Tests for *H. pylori* Infection

	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)
Genedia IgG	96.2	46.1	62.6	92.9
Genedia IgA	91.7	52.5	64.4	87.1
G.A.P IgG	81.8	46.8	59.0	73.3
G.A.P IgA	25.0	85.1	61.1	54.8
Cobas-core IgG	96.9	38.6	59.6	91.5





(cut-off value) , *H. pylori* 141 ( 121 , 20 ) .

, H&E Giemsa *H. pylori* , CLOTM 가 CLOTM 가 *H. pylori* .

Genedia™*Helicobacter pylori* IgG, IgA ELISA, G.A.P test IgG, IgA ELISA, Cobas-core anti-*H. pylori* IgG EIA(2 )

core : , G.A.P IgG Cobas core Genedia™ IgG , G.A.P IgA 가 96.2% 46.1%, Genedia™ IgG 85.1% 가 25% 91.7% 52.5%, G.A.P IgG 81.8% , Genedia™ 46.8%, G.A.P IgA 25.0% 85.1%, Cobas-core IgG 96.9% 38.6% . 20 *H. pylori* Genedia™ IgG 80%, Genedia™ IgA 95%, G.A.P IgG 60%, G.A.P IgA 100%, Cobas-core IgG 75% . : Genedia™ *Helicobacter pylori* IgG, IgA ELISA 가 , , *H. pylori* , *H. pylori* .

: *H. pylori* , ELISA , Genedia™

Genedia™*Helicobacter pylori* IgG, IgA ELISA

kit

G.A.P test IgG, IgA ELISA Cobas-core anti-*H. pylori* IgG EIA (2 ) .

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273

. *H. pylori* 132 (

50 , 52 , 30 )

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